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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,904	01/05/1999	DAVID SIDRANSKY	07265/061002	1766

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**Application No.  
**09/225,904**Applicant(s)  
**Sidransky**Examiner  
**Anne Marie Wehbé**Art Unit  
**1632**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Apr 15, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see NOTE below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

## NOTE:

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached sheet.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1, 7-9, 12-14, 18, 22-26, and 30-36

Note the attached information is used as the state of the art. (See MPEP 2100)

10. ☐ Other: \_\_\_\_\_

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***Attachment to Advisory Action***

The applicant states that the amendment to the claims was made in response to a new rejection put forth by the Office in the final office action, and further requests for withdrawal for finality based on their opinion that comments relating to lack of expression regulatory elements in the claims in the final rejection were not necessitated by amendment. In response, please note that the examiner's comment on page 5 of the final office action regarding expression regulatory elements were made to address the applicant's argument that the claims as amended did not read on any polynucleotide containing a 5'ALT sequence and that the examiner had no objective basis for questioning whether 5'ALT polypeptides are expressed in cells *in vivo*, see page 7 of the response filed on 10/7/02. The examiner did not raise a "new issue" with these comments. The rejection of record under 35 U.S.C. 112, first paragraph, has consistently stated that the specification does not provide an enabling disclosure for using any polynucleotide encoding 5'ALT or 5'ALT operatively linked to exons 2 and 3 of p16 or exon 2 of p15 in the disclosed methods of treating tumors, see pages 3-4 of paper no. 15. Therefore, applicant's request for withdrawal of finality of the previous office action is denied.

Applicant's arguments directed to the pending rejection of claims 1, 7-9, 12-14, 18, 22-26, and 30-36 under 35 U.S.C. 112, first paragraph, are a reiteration of the arguments presented in

Applicant's response dated 10/7/02, and related to the arguments in paper no. 10, see pages 2-7 of the

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identified on pages 2-3, bridging sentence, namely the lack of enablement for treating a cancer associated with decreased p16 expression or 5' ALT /p16<sup>INK4A</sup> expression by local administration at the site of a tumor any polynucleotide comprising SEQ ID NO:1 operatively linked to a polynucleotide comprising exons 2 and 3 of the p16 gene, or for treating a cancer associated with decreased 5' ALT/p15<sup>INK4B</sup> expression by local administration at the site of a tumor any polynucleotide comprising SEQ ID NO:1 operatively linked to a polynucleotide comprising exon 2 of the p15 gene. Therefore, the rejection of record stands.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE PH.D.  
PRIMARY EXAMINER

